

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF ILLINOIS  
EASTERN DIVISION**

In re: TESTOSTERONE	)	
REPLACEMENT THERAPY	)	Case No. 1:14-cv-01748
PRODUCTS LIABILITY LITIGATION	)	MDL No. 2545
	)	
This Document Relates To:	)	
<i>All cases identified in Defendants' First</i>	)	
<i>Corrected Notice of Deficiency (ECF No. 2669-1)</i>	)	

**DEFENDANTS' REPLY IN SUPPORT OF THEIR  
FIRST CORRECTED NOTICE OF DEFICIENCY  
PURSUANT TO CASE MANAGEMENT ORDER NO. 115**

Plaintiffs' Steering Committee's ("PSC") Response in Opposition to the AbbVie Defendants' First Corrected Notice of Deficiency Pursuant to Case Management Order No. 115 (the "Response") fails to appreciate the significance of the deficiency process as contemplated by Case Management Order No. 115 (Cut-off Date for Supplemental Plaintiff Profile Form With Respect to AbbVie Defendants) ("CMO 115") (ECF No. 2519). The process for identifying deficient Plaintiff Profile Forms ("PPF") was intended to streamline this multidistrict litigation by enforcing Plaintiffs' obligations to produce supporting records to substantiate basic allegations of product usage and injuries. As demonstrated by AbbVie's First Notice, filed on May 16, 2018 (ECF No. 2630), and AbbVie's Corrected Notice, filed on May 25, 2018 (ECF No. 2669), the process is working—AbbVie identified deficient PPFs; Plaintiffs provided additional records, amended PPFs, dismissed their cases, and/or otherwise met and conferred, and AbbVie amended its Notice for the Court to act upon. As a result, AbbVie respectfully requests that the Court enter an Order to Show Cause for AbbVie's First Corrected Notice as contemplated by CMO 115.

**I. CMO 115's Meet-and-Confer Process is Working**

Contrary to the PSC's assertion that "half of AbbVie's original deficiency allegations were in error," Resp. at 1, AbbVie's Corrected Notice, which trimmed the number of deficient PPFs from 374 cases to 169 cases, shows precisely that the process is working. The purpose of the meet-and-confer period as outlined by CMO 115 was to ensure that only true deficiencies made their way onto the Court's Order to Show Cause. Of the 374 Plaintiffs on the First Notice, for example, 11 Plaintiffs dismissed their claims entirely; 55 Plaintiffs amended their PPFs to edit their usage and/or injury allegations to match what was documented in their records and/or provided additional records; 88 Plaintiffs clarified that despite the fact that their dispensations records did not substantiate the full alleged usage period, they had indeed produced all pharmacy records. In the last set of cases, AbbVie recognizes that usage may be disputed at a later stage, but for purposes of CMO 115, the deficiency had been cured.

All of this information and additional documentation was the result of the meet-and-confer period. Now that the three day meet-and-confer period has well passed, AbbVie requests that the Court issue an Order to Show Cause as contemplated by CMO 115.<sup>1</sup>

**II. This Court Should Act Upon AbbVie's Deficiency Request**

Rather than turning the deficiency process into a mini-summary judgment proceeding, AbbVie has simply identified a list of cases that have failed to comply with the requirements as stated in the PPF and outlined by various CMOs. CMO 115 requires Plaintiffs "to ensure that they have submitted a PPF and required medical and pharmacy records that are substantially complete

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<sup>1</sup> As of the date of this filing, several Plaintiffs' counsel have continued to reach out to AbbVie's counsel to meet and confer on the Corrected Notice and AbbVie can provide an updated listed removing additional cured cases.

in all respects in compliance with CMO 85.” CMO 115 at 2. For a PPF to be “‘substantially complete in all respects,’ the responding Plaintiff must answer the questions contained in the PPF to the best of his or her ability.” Case Management Order 85 (Supplemental Plaintiff Profile Form – PPF) (“CMO 85”) (ECF No. 2295) at 2. In addition, if “Plaintiff learns that any Defendant has been improperly named in a complaint due to lack of relevant product usage, Plaintiff will, within 21 days of submitting his PPF voluntarily dismiss that Defendant or serve a stipulation for dismissal of that Defendant.” *Id.* The Court again reiterated the significance of providing a full set of records to substantiate the alleged usage period and injury when it dismissed cases for noncompliance with CMO 85: “the PPF required the plaintiff to produce relevant records, *including pharmacy records, regarding the **dispensation*** to and use by the plaintiff of any TRT product and medical records documenting the plaintiff’s claimed TRT-related injuries.” Case Management Order No. 118 (Dismissal of cases for noncompliance with CMO 85) (“CMO 118”) (ECF No. 2612) at 1 (emphasis added).

Specifically regarding allegations of use, the PPF requires Plaintiffs to produce “all records or other information that documents that you or someone on your behalf was *dispensed* prescriptions and/or samples of the TRT products used by you prior to the date of your alleged TRT-related injuries.” PPF at 2 (emphasis added). Despite this unquestionable language in the PPF, which was language the PSC proposed and the Court adopted *see* Case Management Order No. 84 (Enhancement to plaintiffs’ fact sheets; modifications to process for dealing with deficiencies) (“CMO 84”) (ECF No. 2293) at 2, the PSC argues that PPFs are not deficient where “plaintiffs have provided pharmacy records evidencing some but not all of the AndroGel usage alleged in the case,” or where plaintiffs have provided medical records identifying AndroGel as a one of Plaintiff’s medications. Resp. at 2. However, the PPF does not allow pharmacy records to

substantiate *some* of the usage; it requires *all* records of usage prior to the alleged injuries. And the PPF does not allow for other records simply *evidencing* usage; it requires records of *dispensation*. See also Tr. of Nov. 30, 2017 Proceedings (ECF No. 2281) at 5:9-14 (requiring “plaintiffs to include the dispensing information ...[and to] go out and get the pharmacy records”).

Similarly, to substantiate allegations of injuries, the PPF requires Plaintiffs to produce “medical records that show [the] TRT-related injury.” PPF at 4. Nowhere in this language does it allow for Plaintiffs to produce incomplete records for only one of a number of alleged injuries. Yet, the PSC argues exactly that when it states that PPFs are not deficient where “plaintiffs provide medical records evidencing some but not all injuries.” Resp. at 3-4.

Without the Court’s enforcement of this deficiency process, the entire exercise is rendered meaningless. As this Court previously noted, the requirements surrounding the PPF were imposed “to ensure the disclosure of relevant and highly material information needed for the preparation and litigation of the thousands of cases remaining in the MDL,” and “[t]he failure of ... plaintiffs to comply with the PPF requirements of CMO 85 amounts to an unjustified failure to produce discovery following entry of a court order.” CMO 118 at 1-3. However, enforcing the deficiency process does not mean AbbVie is seeking a universal summary dismissal of cases on any deficiency list. Rather, AbbVie is seeking to enforce the requirement that Plaintiffs provide accurate information and supporting documentation to substantiate the alleged usage period and injuries contained in PPFs. Hundreds of Plaintiffs still have yet to provide this basic information that the PSC agreed they should have to provide. See CMO 84 at 2 (adopting Plaintiffs’ proposed PPF for all existing cases in the MDL).

While several cases may be subject to dismissal after undertaking this process, dismissal is not the only appropriate remedy where Plaintiffs have failed to provide the requisite documents.

Other sanctions or remedies may be appropriate as well. At a minimum, however, this Court should act upon AbbVie's deficiency request to address the various types of deficiencies that still remain after the meet and confer. AbbVie will clearly identify for the Court deficient cases where records have not been provided to support the allegations contained in PPFs.<sup>2</sup>

**WHEREFORE**, AbbVie respectfully requests that the Court enter an Order to Show Cause Why the Failure to Comply by May 11, 2018 Should be Excused.

Dated: June 5, 2018

/s/ Michelle H. Yeary

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<sup>2</sup> AbbVie continues to review PPFs and supporting records received and anticipates filing additional deficiency notices this week.

**CERTIFICATE OF SERVICE**

I, Michelle Yeary, hereby certify that on June 5, 2018, the foregoing was filed via the Court's CM/ECF system, which will automatically serve and send notification of such filing to all registered attorneys of record.

/s/ Michelle Yeary